

REMARKS

Applicants submit this response to an Office Action mailed by the USPTO on April 20, 2004. In this response, applicants have amended claims 1, 6, 27, 32, 51 and 57. Claims 7-10, 17, 18, 33-35, 41, 42, 52-54, 58 and 61-65 have been previously presented and remain pending in the present application. In this response and in previously filed responses, applicants have canceled claims 2-5, 24-26, 28-31, 39, 48-50, 55, 56 and 71-73. In previously filed responses, applicants have withdrawn claims 11-16, 19-23, 36-38, 40, 43-47, 59, 60, 66-70 and 74-93. Thus, upon entry of this amendment, claims 1, 6-10, 17, 18, 27, 32-35, 41, 42, 51-54, 57, 58 and 61-65 will be in the present application.

Applicants thank the Examiner for her time spent on a telephonic interview on June 29, 2004. During that interview, applicants' agent and the Examiner discussed the Examiner's rejection of the pending independent claims under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,834,704 to Reinicke. Specifically, applicants' agent took the position that Reinicke discloses making an injection into the peritoneal cavity or other like cavity, with the penetration depth of the needle cannula being limited to about one inch or less. Although not expressly disclosed, it is obvious that the penetration depth must be greater than the skin thickness of the animal (disclosed as a cow or hog), and must also be great enough to penetrate completely through the dermis layer and enter the peritoneal or other similar cavity. A penetration depth limited to the intradermal space, as recited by applicants' claims, would render the apparatus disclosed by Reinicke useless, as a cavity is required to deposit the medication reservoir.

Applicants' agent further took the position that applicants' invention is directed to an intradermal needle assembly that limits penetration of a needle into the skin of a patient during injection to ensure that the drug substance being injected is injected in to the dermis layer of the patient's skin. It is known that the dermis layer of a human's skin is generally in the range of 0.5 mm to 3 mm (variations exist from person to person, and even from area to area on the same person). Reinicke teaches limiting an injection depth to about one inch or less, provided that the injection depth is sufficient to deposit a reservoir in a suitable body cavity. In order for that to occur, the injection depth must exceed the skin thickness of the animal, and certainly cannot limit the injection depth to the dermis layer of the skin. Such an interpretation of the teaching of Reinicke would render that invention inoperable. Thus, applicants' agent took the position that Reinicke does not teach or suggest the invention recited by the pending claims. More specifically, Reinicke does not disclose or suggest an intradermal needle assembly, as defined by applicants' claim 1, for example, comprising, *inter alia*, a needle cannula having a forward tip that extends beyond a generally flat skin engaging surface a distance ranging from 0.5 mm to 3.0 mm.

The Examiner took the position that the disclosure of Reinicke of an injection device having a needle extending about or less than one inch would encompass the range claimed by applicants, and that Reinicke disclosed all structural limitations claimed by applicants. The Examiner recommended that applicant structurally claim the invention to distinguish over Reinicke.

Agreement with respect to the claims was not reached by the Examiner and applicants' agent.

In the Office Action, the Examiner has objected to the drawings under 37 CFR 183(a) as failing to show every feature specified in the claims. Specifically, the Examiner has taken the position that the claim feature of a "plane within about 15 degrees or 5 degrees" is not shown in the drawings. That feature was recited in claims canceled 2, 3, 22, 28 and 29, and in amended claim 51, and is no longer cited in any claim pending in the present application. Thus, applicants respectfully submit that the Examiner's objection is no longer tenable, and respectfully request withdrawal of that objection.

In the Office Action, the Examiner has indicated that claims 5-10, 31-35, 56-58 and 62-63 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants acknowledge and appreciate the Examiner's indication of the allowability of those claims. Applicants respectfully submit that the amendments set forth herein place all claims in the present application in condition for allowance.

In the Office Action, the Examiner has rejected 1-3, 17, 18, 26-29, 41, 42, 50, 51, 53-55, 61, 64, 65 and 73 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,834,704 to Reinicke. In view of the amendments to the claims set forth herein, applicants respectfully submit that the Examiner's rejection of certain claims under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,834,704 to Reinicke is no longer tenable, and respectfully request withdrawal of that rejection.

With regard to claims 17, 18, 41, 42, 64 and 65, applicants respectfully traverse the Examiner's rejection of those claims under 35 U.S.C. §102(b) as being anticipated by Reinicke. Applicants respectfully submit that Reinicke fails to teach or suggest the limitations recited by those claims. Thus, the Examiner's rejection of those claims based upon the teachings of Reinicke cannot be upheld. Applicants respectfully request withdrawal of that rejection.

The Examiner also rejected claims 24, 25, 48, 49, 71 and 72 under 35 U.S.C. §103(a) as being unpatentable over Reinicke in view of U.S. Patent No. 5,672,883 to Reich. In view of the amendments to the claims set forth herein, applicants respectfully submit that the Examiner's rejection of certain claims under 35 U.S.C. §103(a) as being unpatentable over Reinicke in view of U.S. Patent No. 5,672,883 to Reich is no longer tenable, and respectfully request withdrawal of that rejection.

Applicants respectfully submit that all claims pending in the present application, i.e., claims 1, 6-10, 17, 18, 27, 32-35, 41, 42, 51-54, 57, 58 and 61-65, are now in condition for allowance. Applicants respectfully request that the Examiner promptly allow all claims pending in the present application, and permit this application to proceed to issuance.

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Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Amendment and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

Dated: July 20, 2004

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